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10/506,827	09/07/2004	Janusz B. Pawliszyn	PAT 804W-2	8910

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EXAMINER	
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ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
10/18/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/506,827	Applicant(s) PAWLISZYN, JANUSZ B.	
	Examiner Jacqueline DiRamio	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 101-107, 109 and 118-121 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 101-104, 106, 107, 109 and 118-121 is/are rejected.
- 7) ☒ Claim(s) 105 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Applicant's amendments to claims 101, 102, and 105 are acknowledged.

Currently, claims 101 – 107, 109, and 118 – 121 are pending.

Withdrawn Rejections

All previous rejections of the claims under 35 U.S.C. 103(a) have been withdrawn in view of Applicant's amendments and arguments filed August 3, 2007.

Response to Arguments

Applicant's arguments, see p12-13, filed August 3, 2007, with respect to the rejection(s) of claim(s) 101 under 35 U.S.C. 103(a) as being unpatentable over Pompidou et al. (US 6,689,603) in view of Gourley et al. (US 5,120,510) have been fully considered and are persuasive. Applicant's argument that the Pompidou et al. reference fails to teach the coating limited to the end of the "fibre," wherein the "ribbon" taught by Pompidou et al. was compared to the "fibre" of Pompidou et al., is found persuasive. Further, Applicant's argument that Pompidou et al., as well as Gourley et al., fail to teach a "fibre holding region" that is attached to the end of the fibre "opposite to the coated end" is also found persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration of the Pompidou et al. reference, a new ground(s) of rejection is made and presented below.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 101 – 103, 106, 109, and 119 – 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pompidou et al. (US 6,689,603) in view of Gourley et al. (US 5,120,510) and Simpson (US 4,616,652).

Pompidou et al. teach a device for in situ analysis of a substrate, wherein the substrate includes an animal or animal tissue, said device comprising:

at least one rod 1 and support 3 (fibre consisting of a coated end) which is coated with specific antibodies 4 (an extraction phase) for binding (extracting) an antigen (component) present in the substrate; and

a positioning device for guiding said support (coated end) into position within the animal or animal tissue, said positioning device comprising:

an exploration system 5 (catheter) for placement within an animal or animal tissue through which said flexible rod 1 extends, said exploration system having an open end for positioning within said animal or animal tissue and said exploration system being immobilized during sampling with respect to the animal or animal tissue;

wherein said rod (fibre) is a flexible rod (wire) (see Figures 1, and 3-5; and column 1, lines 8-12 and lines 35-65; column 2, lines 2-56; column 3, lines 6-10 and lines 43-59; column 4, lines 4-19 and lines 49-64; column 5, lines 5-19 and lines 40-54; column 6, lines 13-17; and column 8, lines 58-67).

However, Pompidou et al. fail to teach that the support is coated with a polymeric extraction phase, or that the positioning device further includes a rod/fibre holding region attached to the end of the rod opposite to the support (coated end), said holding region being movable with respect to the exploration system (catheter), to move said support of the flexible rod into or out of the blood vessel.

Gourley et al. teach a sensor device comprising an optical fiber for use in sensing the concentration of a component in a medium. The optical fiber 12 contains a sensing element 18, which comprises a coating of a polymeric matrix. The polymeric matrix, which preferably comprises dimethylsiloxane polymers, allows for permeability of the component the concentration of which is to be determined or measured by the sensor system. The fiber and sensing element further contain an overcoating 20, which preferably comprises a cellulosic material (derivatized cellulose). The sensor system is

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created in order to allow for it to be suitable for use in vivo in a human patient.

Additionally, the fiber and sensing element utilizes an optical indicator, preferably a fluorescent dye, which is sensitive to the component of interest and allows for determination of the concentration of the component. Further, the system utilizes one or more optical fibers, which allows for measuring a plurality of different components of interest (see Figure 1; and column 2, lines 60-65; column 3, lines 62-68; column 4, lines 1-60; column 6, lines 39-55; column 7, lines 34-58; and column 9, lines 5-68).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Pompidou et al. the use of a polymeric matrix coating as an extraction phase as taught by Gourley et al. because Gourley et al. teach the benefit of coating a sensor system with a polymeric matrix coating in order to allow for permeability of the component of interest to be measured.

Simpson teaches an insertion guide for a balloon catheter that includes a flexible guide wire 16, a guide tube 12 through which the guide wire 16 extends, an introducer 14, and an enlargement 36 attached to the end of the guide wire. The guide tube is introduced into a blood vessel by sequentially advancing the guide wire, the introducer and the tube until the distal extremity of the tube is positioned adjacent a stenosis after which the introducer and guide wire are removed. The inclusion of an enlargement 36 that is attached to the end of the guide wire opposite from the end that is advanced through the blood vessel allows for the axial and rotative movement of the guide wire, as well as the subsequent removal of the guide wire from the guide tube (see Figure 1; Abstract; and column 2, lines 40-50; and column 3, lines 49-68).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Pompidou et al. a flexible rod (fibre) holding region, or enlargement, as taught by Simpson because Simpson teaches the benefit of including an enlargement at the end of a guide wire that is introduced into a blood vessel, wherein the enlargement is attached to the end of the wire that is opposite from the end of the wire that is advanced through the blood vessel, in order to allow for the axial and rotative movement of the wire, as well as the subsequent removal of the wire from a device inserted within the blood vessel.

With respect to Applicant's claims 102 – 103, it would have been obvious to include an additional coating of a biocompatible layer, such as a cellulosic material, as taught by Gourley et al. because Gourley et al. teach the benefit of including a cellulosic coating with a sensor system in order to allow for the sensor to be suitable for use in vivo in a human patient.

With respect to Applicant's claim 106, it would have been obvious to use a fluorescent indicator with the extraction phase as taught by Gourley et al. because Gourley et al. teach that the indicator is sensitive to the component of interest and therefore, allows for determination of the concentration of the component.

With respect to Applicant's claims 109 and 119, it would have been obvious to use multiple fibers as taught by Gourley et al. because Gourley et al. teach the benefit of multiple fibers in order to allow for measuring a plurality of different components of interest.

With respect to Applicant's claim 120, Gourley et al. teach that the polymeric matrix preferably comprises dimethylsiloxane polymers (see column 4, lines 24-57).

With respect to Applicant's claim 121, Pompidou et al. teach the immobilization of an antibody as a bioaffinity agent to the microsystem in order to selectively bind to an antigen of interest (see Figure 2; and column 2, lines 16-44).

Claim 104 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pompidou et al. (US 6,689,603) in view of Gourley et al. (US 5,120,510) and Simpson (US 4,616,652), as applied to claim 101 above, and further in view of Colburn et al. (US 2003/0183758).

The device of Pompidou et al. meets the structural limitations of both the fiber and extraction phase, therefore, enabling the device to be useful in a variety of analytical instruments, however, Pompidou et al., as well as Gourley et al. and Simpson, fail to teach the use of MALDI-TOFMS analysis specifically.

Colburn et al. teach that matrix-assisted laser desorption/ionization (MALDI) in combination with time-of-flight (TOF) analyzers have become one of the standard approaches to characterization by mass spectrometry of non-volatile, thermally labile substances such as peptides, proteins and polymers (see paragraph 0003, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the MALDI-TOFMS combination as taught by Colburn et al. as the analytical instrument for the device of Pompidou et al., Gourley et

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al., and Simpson because Colburn et al. teach the benefit of using MALDI-TOF analyzers because they have become one of the standard approaches to characterization by mass spectrometry of non-volatile, thermally labile substances such as peptides, proteins and polymers.

Claims 107 and 118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pompidou et al. (US 6,689,603) in view of Gourley et al. (US 5,120,510) and Simpson (US 4,616,652), as applied to claim 101 above, and further in view of Pawliszyn (US 5,691,206).

Pompidou et al., Gourley et al., and Simpson fail to teach that the device comprises an openable housing for said flexible rod (fiber), wherein said housing can comprise a needle.

Pawliszyn teaches a device for solid phase microextraction comprising a fiber 6, which contains a polymeric coating selective for a component of interest (extraction phase), and a metal sleeve 24 and hollow needle 18, which houses the fiber. The purpose of the housing of the fiber by the metal sleeve and hollow needle is to protect the fiber from damage when not in use. The device is enabled for solid phase microextraction in both in-vivo and in-vitro samples, wherein said polymeric coating is chosen based on its selectivity for a target component present in a sample carrier (see Figures 1 and 2; and column 2, lines 10-21; column 3, lines 5-16; column 5, lines 10-15; and column 7, lines 33-53).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Pompidou et al., Gourley et al., and Simpson an openable housing comprising a needle for housing the flexible rod (fibre) as taught by Pawliszyn because Pawliszyn teaches the benefit of housing a fiber for use in in-vitro or in-vivo sampling for extraction purposes in order to protect the fiber from damage when not in use.

Allowable Subject Matter

Claim 105 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the


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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jackie DiRamio
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